A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy and Safety of Obinutuzumab in Patients with ISN/RPs 2003 Class III or IV Lupus Nephritis (REGENCY)

Status: Not yet recruiting

Eligibility Criteria

Sex: All
Age: 18 Years to 75 Years old
This study is NOT accepting healthy volunteers

Key

Inclusion Criteria:
• Diagnosis of active or active/chronic ISN/RPS 2003 Class III or IV proliferative LN as evidenced by renal biopsy performed within 6 months. Participants may co-exhibit Class V disease in addition to either Class III or Class IV disease
• Urine protein to creatinine ratio greater than or equal to (≥) 1 on a 24-hour collection
• Other inclusion criteria may apply

Exclusion Criteria:
• Pregnancy or breastfeeding
• Severe renal impairment or the need for dialysis or renal transplantation
• Receipt of an excluded therapy, including any anti-CD20 therapy less than 9 months prior to screening or during screening; or cyclophosphamide, tacrolimus, ciclosporin, or voclosporin during the 2 months prior to screening or during screening
• Significant or uncontrolled medical disease which, in the investigator's opinion, would preclude patient participation
• Known active infection of any kind or recent major episode of infection
• Intolerance or contraindication to study therapies
• Other exclusion criteria may apply

Conditions & Interventions

Interventions:

Conditions:
Lupus Nephritis

More Information

Description: Study to Evaluate the Efficacy and Safety of Obinutuzumab in Patients with ISN/RPS 2003 Class III or IV Lupus Nephritis
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Phase: Phase 3
IRB Number: STUDY00010015
System ID: NCT04221477

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